DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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APR 1 2005

Laohman Consultant Services, Inc.
Attention: Robert W. Pollock
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

Docket No. 2003P-0331/CP1

Dear Mr. Pollock:

This is in response to your petition filed on July 23, 2003, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Hydrocodone Bitartrate and Ibuprofen Tablets, 5 mg/400 mg, 7.5 mg/400 mg, and 10 mg/400 mg. The listed drug product to which you refer in your petition is Vicoprofen® (Hydrocodone Bitartrate and Ibuprofen) Tablets, 7.5 mg/200 mg, NDA 20-716, held by Abbott Laboratories.

Your request involves a change in strength of the ibuprofen component (from 200 mg to 400 mg) and a change in the hydrocodone bitartrate component (from 7.5 mg to 5 mg and 10 mg) from that of the listed drug product. The changes that you request are the type of changes that are authorized under Section 505(j)(2)(C) of the Act.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Sections 505(j)(2)(C)(i) of the Act such a petition will be approved unless the Food and Drug Administration (FDA) finds that investigations must be conducted to show the safety and effectiveness of the proposed drug products, or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug product.

The FDA has determined that your proposed changes in strength raise questions of safety and effectiveness, and has concluded that clinical trials are required for this specific drug product. The FDA has concerns that there is no safety information to support the proposed dosing of a product containing hydrocodone bitartrate and ibuprofen in a 10 mg/400 mg combination. Furthermore, the proposed change in the dose of hydrocodone bitartrate and ibuprofen to 5 mg/400 mg, 7.5 mg/400 mg, and 10 mg/400 mg reduces the ratio of hydrocodone bitartrate to ibuprofen. As such, the relative contribution of the hydrocodone component to efficacy of the combination drug product cannot be assumed to be the same as the efficacy of the product with the original ratio of components. The new ratio may mean that most or all of the analgesic efficacy is contributed by the ibuprofen component such that the presence of hydrocodone is unnecessary. Please refer to 21 CFR 300.50 regarding combination drug products. In addition, the proposed changes may result in a product with the accompanying risks of abuse, misuse and

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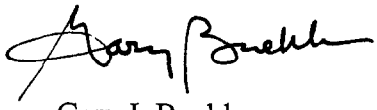
diversion for this Schedule III narcotic (i.e., hydrocodone bitartrate) contained in the combination drug product without the benefits derived from its addition. Therefore, FDA is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the proposed drug product. Please contact the Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products at (301) 827-2040 if you wish to pursue approval of your product under Section 505(b) of the Act.

If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the FDA to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research